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Our Members

Ordinary Members

Allergan Australia Pty Ltd
Aventis Pharma
Bayer Australia Ltd Consumer Care
Business Group
Biovital Pty Ltd
Boehringer Ingelheim Pty Ltd
Boots Healthcare Australia Pty Ltd
Carter-Wallace (Australia) Pty Ltd
Colgate-Palmolive Pty Ltd
Combe International Ltd
Dermatech Laboratories Pty Ltd
Ego Pharmaceuticals Pty Ltd
Estee Lauder Pty Ltd
Faulding Healthcare Consumer
CB Fleet Co (Australia) Pty Ltd
Galderma Australia
GlaxoSmithKline Consumer Healthcare
H W Woods Pty Ltd
Janssen-Cilag Pty Ltd
Mentholatum Australasia Pty Ltd
Merck Sharp & Dohme (Aust) Pty Ltd
Novartis Consumer Health Australasia Pty Ltd
Pfizer Pty Ltd
Pharmacia Australia Pty Ltd
Reckitt Benckiser
Roche Products Pty Ltd
R P Scherer Holdings Pty Ltd
Smith & Nephew Pty Ltd
Soul Pattinson (Manufacturing) Pty Ltd
Stiefel Laboratories Pty Ltd
Taisho Australia Pty Ltd
3M Health Care Pty Ltd
Whitehall Laboratories Pty Ltd
Whiteley Industries Pty Ltd

Associate Members

Bates Healthworld Pty Ltd
Cellegy Australia Pty Ltd
Contract Pharmaceutical Services of
Australia Pty Ltd
Cormack Packaging Pty Ltd
Curtis Jones & Brown Advertising Pty Ltd
Engel, Hellyer & Partners Pty Ltd
Grey Healthcare Group
Hahn Healthcare Recruitment
Hammond & Thackeray Pty Ltd
IMS Australia Pty Ltd
McCann Healthcare
Medi Kwik Pty Ltd
Nature's Herbals
Pharmaceutical Professionals Pty Ltd
PharmAction Holdings Pty Ltd
Reader's Digest Australia Pty Ltd
Regulatory Concepts Pty Ltd
Singleton Ogilvy & Mather
Sudler & Hennessey
Sue Akeroyd & Associates
Technical Consultancy Services Pty Ltd

Honorary Lifetime Members

Mr A. D. Glover
Mr A. J. Wardell
Dr W. A. Morgan
Mr D. C. Murphy
Dr J. Pentecost
Mr W. J. Wilkinson AM
Mr C. J. Tucker

Our Mission

“ Better health through responsible self-medication ”

Our Vision

“ ASMI - the one voice of the Australian non-prescription consumer healthcare products industry, nationally and internationally - supports a credible and expanding self-medication market, generating cost-effective health solutions. ”

David Armstrong Reckitt Benckiser

Geoff Bolland R P Scherer Pty Ltd

Mark Bowden Pfizer Pty Ltd

Kevin Darke GlaxoSmithKline Consumer Healthcare

Denis Dikschei CB Fleet Co (Australia) Pty Ltd

John Gurney Mentholatum Australasia Pty Ltd

Trevor Juniper Pharmacia Australia Pty Ltd

Steven Mann Faulding Healthcare Consumer

David Murphy Combe International Ltd

Alan Nash Carter Wallace (Australia) Pty Ltd

Elizabeth Treble Aventis Pharma

Sue Williams Boots Healthcare Australia Pty Ltd



ASMI Committee of Management

Our President's Review of the Year



It is my pleasure to report to you on the 2000/2001 year of your industry association.

This was, of course, our first year as the Australian Self-Medication Industry (ASMI), and it turned out to be a year full of firsts. For instance, for the first time in a decade, our Committee of Management election was contested, resulting in a superior balance of representing Member companies in terms of business size, location, grocery/pharmacy mix, and product diversity. This balance comes with new blood, a younger demographic and every indication of vitality.

It was also the year we launched a new strategic plan with its commitment to One Voice for our sector. Three new Members joined our number, Taisho (Australia) Pty Ltd, Medi Kwik Pty Ltd and Pharmaceutical Professionals Pty Ltd. These new Members added to our strength and highlighted the challenges and opportunities of emerging distribution channels.

Our keen focus on achieving the objectives set out in our Strategic Plan is paying off in measurable achievements for industry. Another section of the Annual Report outlines these achievements more fully, but I will mention some of them here.

The fiscal year began with the smooth, cost-effective transition to our new name and logo. Within a matter of months our website (launched in January 2000) had not only made the transition to our new livery, but also sported a Members-only section and was contributing to our sharper communication focus with better feedback channels. Via the website and e-mail the Secretariat provided Members with value for their subscription dollar by instituting fast and cost-effective communication strategies. As part of putting our house in order, the ASMI Rules were modernised this year to produce an easier-to-use reference document.

Great energy was applied to activities supporting our objective to improve access for our brands.. The trend toward a heavy load of reviews continued this year. The Secretariat made a pre-budget GST submission to the Federal Government as well as submissions to the Regulatory Reform Taskforce, the Productivity Commission Review on Cost-Recovery Arrangements and the Trans-Tasman Single Agency project. Reviews from last year required continuing attention. For instance, ASMI this year made additional representations to the National Review of Drugs Poisons and Controlled Substances Legislation (Galbally).

From a company perspective, what does all this activity mean? It means we derive commercial benefit from the on-going process of trans-Tasman harmonisation. It means that we are working toward making the National Drugs and Poisons Schedule Committee (NDPSC) a more flexible body that is truly representative. It means that we have input into the redevelopment of the Electronic Lodgement Facility (ELF) and therefore are improving the way listable products make it to market. ASMI has also been working to refine the OTC registration evaluation process, thus making market entry a more efficient process. Our membership of the Medicines Partnership of interests can be pursued in a strong, collective manner.

Not all of the Association's activities are focused on reviews, of course. For many years we have been proactive in areas in which government and other stakeholder groups have not. This year, two of these areas have been shown to be so critical that our guidelines are now the basis for industry-wide

approaches, namely our Crisis Management Guidelines and Tamper Evident Packaging Guidelines.

This was also the year that ASMI brought the world to Sydney. In all, just over 400 participated in the 4th Asia Pacific Regional Conference of the World Self-Medication Industry. Twenty-six countries were represented. The commercial outcomes will continue into the future. Just some of the outcomes of the conference included the signing of the break-through Sydney Declaration by the participants of the regional Regulators' Forum on which we worked closely with TGA. We will see other commercial outcomes from the areas outlined in the speeches of Dr Stewart Jessamine on trans-Tasman progress, the several compelling talks on the future of complementary medicine and the predictions on the impact of the application of technology in our sector.

The Conference was not our only opportunity to be face-to-face with the Membership. This year we held dinner meetings with Members in Melbourne and Sydney, free breakfast seminars, made many company visits and held a series of "think tank" meetings with Members. We have met

with many politicians and regulators influential in our sector and I am personally pleased with the high level of credibility our Association has developed and the high regard held for the Secretariat of ASMI. Our learnings from these meetings guide our pursuit of our strategic objectives.

In considering our own business environment, we must also consider appropriate changes to the ASMI Code to ensure that we have a workable and ethical Code that still allows vigorous yet responsible competition in today's highly competitive environment. This task has been assigned to the Marketing and Ethics Subcommittee.

Our achievements reflect Members and the Secretariat working in a co-ordinated way through a period of extensive change. The way ahead must be equally consultative and participative. A very high percentage of companies have representation within our committee and subcommittee structure. There is always room for more.

Kevin Darke
ASMI President

Juliet Seifert Executive Director
Zephanie Jordan Scientific Director
Deon Schoombie Advertising Services Manager
(through April 2001)
Mary Emanuel Regulatory & Technical Manager
Jonathan Breach Regulatory & Technical Manager
– Complementary
Monica Johnstone Member Services Manager

Montse Pena Advertising Services Adviser
Wendy Long Office Manager/Executive Assistant
(through April 2001)
Lucy Castro Office Manager/Executive Assistant
(from April 2001)
Michelle Johnston Office Assistant
(through May 2001)
Robyn Kirkness Reception (P/T)



Front row from left: Juliet Seifert, Montse Pena. Back row: Alexandra Macvean, Mary Emanuel, Monica Johnstone, Robyn Kirkness, Lucy Castro. Not pictured: Jonathan Breach and Zephanie Jordan

How does your **Garden** **Grow?**

An Association with a Sustainable Future

The title of the 2001 ASMI annual conference (*2008: a Healthcare Odyssey*) pays homage to Arthur C. Clark's *Space Odyssey*. Clark remains to this day a futurist as much as he was a quarter century ago when he wrote about our year, 2001, and sowed a seed in our imaginations.

In a recent article for *Reader's Digest*, Clarke maintains that what he does is "outline possible 'futures'—although," he admits, "totally unexpected inventions and events can render predictions absurd after only a few years".

For our conference, we chose to outline futures not so very far from us in time. A mere seven years down the track, it is the foreseeable future, the future we must plan for now, that is our object.

2008 is a year that Clarke predicts will see "a city in a third world country [...] devastated by the accidental detonation of an atomic bomb in its armoury." He goes on to say of this momentous year that "After a brief debate in the United Nations all nuclear weapons are destroyed." Preposterous? Maybe not—for those who are not 'imagination challenged', it is conceivable that the UN could have a short debate on something.

Another pundit, with a certain interest in the future, has said that "We always overestimate the changes that will occur in the next two years and underestimate the changes that will occur in the next ten". Much as we may hate to admit it, Bill Gates may well be right.

Ready, Steady, Grow

Just as Industry must strive not to over- or underestimate change, so too must the Association build in the flexibility to deal with the unexpected and the strength to maximise the benefits of those trends that are predictable. Just as the future of self-medication is linked to managing costs in healthcare, so too is the sustainability of the Industry Association linked to maximising our value to Members while containing costs.

During the last year, ASMI has asked itself what change is necessary and desirable to be vital and relevant in the foreseeable future. The answer to that question and the actions that answer engendered are our subject here.

With the results of the Member Survey completed toward the end of the financial year 1999/2000 and the unanimous vote to adopt the new name Australian Self-Medication Industry on 8 June 2000, the newly branded ASMI set forth into the financial year 2000/2001 with many great hopes to realise.

Our change of name and livery were taken up with great enthusiasm. Terry Slater, National Manager of the Therapeutic Goods Administration (TGA), in a luncheon address only minutes after the unanimous vote, welcomed the change and made "ASMI" sound like a household name. Coverage in the trade press of the change was good. Congratulations on our new look arrived from international

and domestic contacts. Office stationery and the website were adjusted quickly.

All that was left to do was the hard part, live up to the potential signalled by the “new look”. This involved the hard realisation that a sustainable future must be built, that it was unlikely to occur through a *laissez-faire* approach.

The ASMI Executive raised the issues relating to future viability and provided direction. The Committee of Management challenged the Secretariat Team with drafting a new Association structure that would provide employment for the existing Secretariat in a way that maximised the knowledge and skills already there and made future development possible. The Committee also wanted the final picture to reflect the objectives of the strategic plan by allocating resources accordingly. It was also made imperative that the final plan reflect future financial realities such as the merger of Member companies, tighter company budgets and heavier workloads, and shifts in the sponsorship climate.

The Hardware, the Software and the Wetware

The “do more better with less” message was received and the Secretariat set itself to the task. Through a process of brainstorming, drafting, revision, consultation with Committee of Management and further refinement, a new structure meeting the criteria was proposed.

Carefully recruited personnel soon filled the slots vacated through natural attrition. The new Administration Coordinator relieved others in the Secretariat of certain administrative duties so that greater emphasis could be placed on their advertising, membership or regulatory and technical projects. This new role also provided a needed cross-reference between the various subcommittees, special teams and working parties that are vital to the Association. This key new function is a kind of glue for the rest of the Secretariat and the most obvious part of our commitment to improved knowledge management.

Another position was created, to be brought on board early in the 2001/2002 financial year. The new Marketing and Development Director will provide a higher level of Member and stakeholder contact than has been possible thus far in the Member Services area. This new Director will help us to expand the Membership to secure our objective

of “one voice”. This role will also facilitate the development of additional targeted opportunities for the Membership that speak to needs uncovered in the Member Survey as well as those mandated by the Strategic Pplan. The three directors and the elected officers together will provide the most public face of the ASMI.

This team will also seek to strengthen networks and to build opportunities for partnerships and explore alternative funding opportunities.

To maximise the effectiveness of the newly constituted team, a major Information Technology project was undertaken, not to buy new hard- and software, but to optimise the use of the existing systems after they were assessed to be appropriate to the task. The Membership database is now capable of providing more tailored information so that Members are better served. During this process, the “wetware” (that is, the users of the systems at ASMI) have received valuable training in more sophisticated use of the optimised systems.

Members have made a valuable contribution to this process of optimisation through their willingness to provide information. The Secretariat is conscious that the privacy of this data is important. Early in the financial year 2001/2002, privacy policies will be refined in line with the new Privacy Legislation which comes into effect at the end of 2001.

What is our Voom?

The refinement of systems is laudable, but Members are entitled to understand to what end. To the end of improving what is our unique value proposition to Members: that we can supply for Members what they cannot acquire for themselves, cost-effectively or at all.

Recently, an active Member participant on a number of ASMI regulatory subcommittees decided to take a sabbatical from her job to recharge her batteries. She told the Secretariat that she would miss working on subcommittees that accomplish such a high percentage of their goals. Facilitating that sort of empowerment was part of what ASMI was seeking in its recent changes.

What is the nature of that empowerment? An analogy is in order. Many will remember that at the end of the children's story *The Cat In The Hat Comes Back* by Dr Seuss, the solution to the persistent problem “(which is that story's plot device)”

turns out to be “Voom”. While the book ostensibly teaches children the alphabet, one might also say it argues that we must go beyond that lesson to something a little more valuable, more capable and harder to quantify. It is that powerful and dynamic force that puts your house in order when chaos seems inevitable. The good doctor, through the character of the Cat, tells us that “Voom is very hard to get and you never saw anything like it, I bet.”

At its best, an Industry Association has Voom that sways policy, moves mountains of red tape, creates more favourable environments, brings together stakeholders, works through seemingly intractable regional difficulties, levels the playing field, spares companies from unwanted media attention and court costs, provides opportunities that might otherwise never have crossed the desks of company employees, alerts Members to dangers, and provides answers to thousands of questions each year in industry-wide contexts.

For almost all Member companies, the price of this Voom is far less than one would pay to add one middle manager to the payroll. Voom is a very special kind of outsourcing.

In most outsourcing, a company preserves its core mission and pays outside companies to provide IT, HR or other services—often at the considerable expense of having to attempt to bring each of these service providers up to speed on the nature of the business, its quirks, its players, its values, its complexities.

An optimised industry association already knows the business. In fact, the Association is a source of business information; provides briefings on the issues; gathers the key players; codifies the values; and provides conferences, publications, think tanks and other resources to make sense of the complexities. These features are standard. There is no billing by the quarter hour. No premium on call outs.

Gardening the Knowledge Bank

Instead of tapping into a single service provider, Members are accessing a knowledge bank. This is vital because, as Prof Thomas Clarke put it in a recent issue of *Australian Standard*, “Knowledge is becoming recognised as both the foundation of competitive advantage and the basis of market capitalisation.” In our context, knowledge is both differentiation and the power of influence. These attributes can only be maximised collectively—no one company can have individually what we have together as an industry with a unified voice, the access to processes we have earned over the last decade or more, and the partnerships we have built over that period.

While we enjoy these fruits now, we must continue to do the spadework that keeps the garden thriving. And, just as a modern gardener might rotate a vegetable patch and put in a high tech sprinkler system, nurturing what we have now into something even better involves the occasional structural change and technical tune-up. To rest on one’s laurels is certainly to see them wilt.

To be a good gardener, the Association must recognise needs and pull some weeds. Through growing our activities and pruning processes we are doing both. And though there is no *Farmer’s Almanac* to guide the planting schedule in Association work, timing is key. Responsiveness to Members is vital in the fast changing environment of the market today.

Trend spotting

Even the most casual observer will note that spotting the trends today and making useful forecasts is harder now than it once was, largely due to the pace of economic change and the emergence of new

technologies. Who would have foreseen 18 months ago that the much touted decentralised IT models with a “broadband glut” making possible far-flung networks could possibly ever swing back to the point that *The Economist* would report, as it did in late July, that “mainframe computing may be making a comeback.”¹ In other words, the advent of a new approach like that taken in Linux could change the whole orbit in a direction that might otherwise seem retrograde.

With the advent of entirely new sort of technological networks, we are in a good position to explore the sorts of synergies that could come from virtual private networks within the partnerships we have created.

The rabbit we must pull out of our hat is not just which technology to apply, but how to do it a way that is truly adequate to the human element of the task. It has been reported that two-thirds of customer relationship management projects fail. “The trick is not merely to cut costs, but also to retain old fashioned values of customer service.”² In this regard the Association is fortunate. We have the directions set by our elected Committee and the check provided by our Member Survey. We have our Code of Practice and our commitment to the National Medicines Policy and Quality Use of Medicine principles to guide us.

Avoiding technology will not secure customer service values either. The Head of General Motors concedes that almost all prospective car buyers check the Internet before buying a car. Internationally, the data coming from industry associations in our sector shows that those with health concerns are also checking the Internet. Doctors are piloting secure e-mail communications with their patients.

In addition, the popularity of technologies that offer access to information will make them astounding tools for information gathering as well. And yet, we must know what to do with the great pools of data that form. There are privacy issues, internal issues of competition over data within companies, and the more ‘garden variety’ issue of just making some sense of it all. In the case of ASMI, that sort of sense-making will come from the human resources of our Secretariat and our Membership.

That is why we have rearranged the Secretariat under three directors with clear areas of responsibility and supporting teams consciously linked together to form a self-supporting human network. This human network has been matched to

appropriate technological networks so that the Association may be of greatest benefit to the Membership and the cause of *better health through responsible self-medication*.

All in a row

That is how the garden grows in 2001. With flexibility and strength stemming from carefully matched people and systems and the scalability to develop both.

It is our design that our plantings now will continue to bear fruit into the future. It is our intention to deliver “Voom” in a timely fashion to a growing Membership. We look forward to the challenge.

The fruition of this work will be for the benefit of the Membership and the projects that combine to achieve our strategic objectives. With the reallocation of resources, ASMI is better equipped to work for our principles in the marketplace such as

GST-free status for all medicines;

consumer medicines that are reliably safe and effective and also cost-effective in order to deal with ailments with minimal delay while avoiding burdening health services;

Government’s stated commitment and action to shift appropriate medicines from prescription to non-prescription;

Government’s stated commitment to subsidising non-prescription medicines where justified (which would form part of the company’s incentive to switch); and

Exclusivity for companies undertaking trials to generate evidence for switch of products off patent (which would form another part of a company’s incentive to switch).

These are just a single bouquet gathered in a large garden, but these goals are the type of outcomes that our new skill sets and efficiencies are honed to deliver.

1 The Economist, 21 July 2001, page 52.

2 The Economist, 14 July 2001, page 9.

Our Achievements through the year

The major achievements of the year were reported directly to Members in the second edition of *For the Record*, which was mailed to all company official representatives and made available on the Members section of the ASMI website. The achievements listed here are highlights from *For the Record* as well as achievements that occurred after it was published but before the end of the 2000/2001 financial year. The achievements are grouped in terms of the primary strategic objective that they helped to secure.

Maximise Freedom of Access

This objective sets out to establish and maintain a harmonised system of product access, which provides consumers with equal and appropriate availability to non-prescription medicines.

In order to achieve this, we continue to work in the areas of advertising reform, streamlining of regulatory processes and tax reform.

- ❖ **Accomplished the published revision of the first chapter of the Australian Guidelines for the Registration of Medicines** and agreed with TGA the priorities for review of the next chapters. The revised guidelines provide sponsors with greater clarification of the regulatory requirements to facilitate market entry.
- ❖ **Achieved refinements to the OTC registration evaluation process**, making it more transparent and predictable to facilitate market entry.
- ❖ **Initiated discussions with the Office of Complementary Medicines**, with a view to improving processes in terms of transparency and predictability and to develop guidelines to clarify the criteria for new product and substance applications. This effort was rewarded with a strengthened relationship with that office.
- ❖ **Commenced review of NDPSC Guidelines** to clarify and resolve process issues.
- ❖ **Involved in TGA Business planning for 2001/2002** to see the plan reflect ASMI key priorities for improvements in the OTC Medicines Evaluation Section, the Office of Complementary Medicines and the National Drugs and Poisons Schedule Committee.
- ❖ **ASMI recognised as a key stakeholder in the redevelopment of the Electronic Lodgment Facility** as it moves from a disk-based system to a more easily updated on-line interface with improved features for industry and increased focus on post-market monitoring.
- ❖ **Submissions** made to the Regulatory Reform Taskforce, Productivity Commission Review on Cost Recovery Arrangements, the Trans-Tasman Single Agency Project, the Federal Budget.
- ❖ Continued representations to the **National Review of Drugs Poisons and Controlled Substances Legislation (Galbally Review)**.
- ❖ Continued negotiation and pushing saw the revision of the TGO 48 Labelling Order (to be replaced by TGO 69) finalised in June 2001.

Sustain a Supportive Service Environment

This objective commits us to working to ensure not only optimal communication within the Secretariat but also between the Association and its Members and with all relevant stakeholders. To best do this, we are continuously working to increase our usefulness to Members as a source of vital and credible information.

- ❖ Appointed a permanent full-time **manager in the Regulatory and Technical area with a focus on complementary healthcare products** to provide services in this expanding area of the Membership.
- ❖ **ASMI website expanded** as it made the transition from a small “brochure” PMAA website to a much larger ASMI site with a password-protected Members Section. This development was achieved at no additional hosting charge and with minimal development cost. See final page of the report for details.
- ❖ **ASMI Legislation Service refined and provided electronically.**
- ❖ **ASMI Newsletters** (*One Voice, R&T Express and RE:claim*) **provided electronically** and made available on the ASMI website.
- ❖ **Publications and website delivered an increased focus in the complementary healthcare products area.**
- ❖ **ASMI staffers profiled to the Membership in the “ASMI Profile” column of One Voice**, increasing Members’ awareness of the Secretariat.

Achieve a Whole-of Industry Approach to the Quality Use of Medicine

This objective seeks to promote the quality use of medicines to all relevant stakeholders to secure commitment to performance-based approaches to regulation.

- ❖ **Implemented industry-wide Crisis Management Guidelines and Tamper Evident Packaging Guidelines**, which were developed from ASMI’s proactive work. The Crisis Management Guidelines provide a level of consistency in the management of tampering crises across the industry. The Tamper Evident Packaging Guidelines will ultimately be underpinned in the therapeutic goods legislation to ensure a level playing field.
- ❖ **Submission made to Standards Australia on a new UVA sunscreen testing method** and featured this method in a Sunscreen Seminar. The method, if accepted, will be

incorporated into the Australian Standard. It is hoped Australia can influence decisions elsewhere in the world on the most appropriate UVA test to use and that Australia be recognised for expertise in sunscreens.

- ❖ **Lobbying efforts promoted performance-based labelling coming to fruition** in the TGA Labelling Project discussion paper that leans toward a performance-based system. Industry continues to promote a more flexible system with measurable benefits for consumers’ understanding of their medicines.
- ❖ **The new structure of ASMI sees our commitment to QUM strengthened.**

Broaden the Relevance and Influence of the Association

This objective is designed to secure the Association’s future as the peak body representing the entire spectrum of the self-medication industry in Australia.

- ❖ **Continued to represent industry on key external committees**, such as the Medicines Evaluation Committee, Australian Pharmaceutical Advisory Committee, NSW Poisons Advisory Committee, ELF Project Advisory Committee, Joint Herbal Task Force, External Reference Panel on Interface Matters, Therapeutic Goods Committee (as well as representation on its subcommittees: Labelling, GMP & CRC), Standards Australia Sunscreen and CRC Subcommittees, Victoria Roads and Safety, TGA’s Strategic Information Management Environment (SIME), Medicines Evaluation Subcommittee for the revision of the Australian Guidelines for the Registration of Medicines, APAC Subcommittee on the misuse of medicines, Quality Assurance Reference Group, Complaints Resolution Panel, Therapeutic Goods Administration Industry Consultative Committee, Crisis Management Taskforce, Therapeutic Goods Advertising Code Council, PHARM Communication Subcommittee, S2/S3 Project Group, APF Editorial Board.
- ❖ **Achieved position of alternate representative on the National Drugs and Poisons Schedule Committee.**
- ❖ **Developed and implemented for industry an educational website on the National Packaging Covenant** to assist Members with compliance with the National Environment Protection Measures legislation. Set up workshops with the Advanced Manufacturing Centre to provide the facility for Members to develop action plans for compliance.

Outcomes of Complaints lodged under the ASMI Code of Practice 2000/2001

Lodging complaint: Novartis Consumer Health Australasia Pty Ltd

Against: Janssen-Cilag Pty Ltd

Complaint: Advertising and promotion of DaktaGold to consumers and healthcare professionals

Alleged breaches: Clause 5.1.4 of the ASMI Code of Practice – failed, without delay upon receipt of a bona fide request, to provide substantiation of claims made in an advertisement comprising a detail piece for Janssen-Cilag's DaktaGold anti fungal cream.

Outcome: The complaint was justified. The Complaints Panel found this to be a minor breach and has an undertaking that Janssen-Cilag provide the substantiation sought by Novartis.

Lodged complaint: Pharmacia & Upjohn Pty Ltd

Against: SmithKline Beecham Consumer Healthcare

Complaint: Pharmacy Trade presenter and an advertisement in Pharmacy Trade directed at Healthcare Professionals.

Alleged breaches: Clauses 4.3.1, 5.1.3, 5.1.4 and 5.2 of the ASMI Code of Practice – alleged unsubstantiated claims of superior patch technology; unsubstantiated comparative claims of better craving control; unsubstantiated comparative claims of lower urge to smoke.

Outcomes: Alleged breach in relation to unsubstantiated claims with regard to "better craving control due to superior patch technology. Panel found that craving control advantage claimed for Nicabate over Nicorette was not due to any advanced technology thus this representation was found to be in breach of Clauses 5.1.3 and 5.1.4 of the ASMI Code. Alleged breach in relation to comparative claims with regard to "better craving control". The summary provided in substantiation of this claim did not contain sufficient information about the design and conduct of the study and hence clause 5.1.4 of the ASMI Code has been breached. Alleged breach with regard to unsubstantiated comparative claims of lower urge to smoke – The Panel found this claim to be unsubstantiated and in breach of Clauses 5.1.3 and 5.2 of the ASMI Code. The Complaints Panel required the undertaking to discontinue publication of the advertisement, to retrieve all copies of the trade presenter and publish a corrective statement.

Appeal lodged: SmithKline Beecham against the decision of the Panel.

Complaint - "better craving control due to superior patch technology". The arbiter found the Panels' decision justified.

Complaint - comparative claims with regard to "better craving control". The arbiter found the Panels' decision justified.

Complaint - comparative claims of lower urge to smoke, the arbiter found the Panels' decision justified.

Lodged Complaint: Schering-Plough Pty Ltd

Against: Warner Lambert Consumer Health Care

Complaint: Advertising and promotion of Zyrtec to consumers and healthcare professionals.

Alleged breaches: Clauses 5.1.3 and 5.1.4 – Alleged incorrect statement regarding approved indications for use of Telfast, lack of substantiation for onset of action for Claratyne, lack of substantiation for comparative claim regarding efficacy of Zyrtec over Claratyne .

Outcomes: The Panel found that the alleged breach of Clause 5.1.3 of the ASMI Code – incorrect statement regarding approved indications for use of Telfast – to be justified. The Panel found that the alleged breach of Clause 5.1.4 of the ASMI Code, regarding onset of action for Claratyne, to be unjustified. The Panel found that the alleged breach of Clause 5.1.4 comparative claim regarding efficacy of Zyrtec over Claratyne to be unjustified.

Lodging complaint: Janssen-Cilag Pty Ltd

Against: Bayer Australia Pty Ltd

Complaint: Promotion of Canesten Antidandruff Shampoo to consumers.

Alleged breaches: Clauses 4.3.1, 5.1.4 and 5.2 –alleged misleading representation of the effectiveness of Canesten Antidandruff Shampoo and the non provision of substantiation of claims upon bona fide request.

Outcomes: The Panel found that the alleged breaches of Clauses 4.3.1 and 5.2 of the ASMI code with regard to the misleading representation of the products effectiveness to be justified. The Panel found that the alleged breach of clause 5.1.4 with regard to the provision of substantiation to be justified. The Complaints Panel required the undertaking to discontinue publication of the advertisement, retrieve all copies of the advertisement that may be in circulation and to issue a corrective statement (including the determination of the Panel) to all pharmacies which received the advertisement. In addition the Panel imposed a fine.

Appeal lodged: Bayer

Against: The determinations of the Panel

Outcomes: The arbiter modified the Panels' decision that the determination be sent to all Pharmacies along with a corrective statement. All other decisions of the Panel were upheld.

Sydney 2000 Declaration

Regional Regulators' Forum

*Hosted by the Therapeutic Goods Administration and held in association with the World Self-Medication Industry 4th Asia Pacific Regional Conference
23 November 2000 • Sydney, Australia*

During November 2000 the regulators of therapeutic goods from 14 countries of the Asia Pacific region met at a Regulators' Forum in Sydney, Australia.

The Regulators' Forum considered many current issues and shared information and experiences about the regulation of the self-medication industry. In doing so, the Forum recognised that self-medication, for appropriate conditions, is an important first line of health management in the health care community. It was acknowledged that responsible self-medication provides positive health outcomes for individuals, as well as positive consequences for society as a whole.

The Regulators' Forum recognised that the global nature of the therapeutic goods industry has opened the way for greater information exchange between governments, industry, regulators and consumers. It was acknowledged that in a complex and innovative environment, the ability to respond in a positive and farsighted way is an important feature of international information exchange and a measure of success in harmonising approaches.

The Regulators' Forum considered seven themes as key elements in supporting improved and transparent decision making in order to assist in achieving quality health outcomes.

In so doing they recognised the need to:

- ❖ foster partnerships and promote potential regional collaboration through the encouragement of both bilateral and multilateral cooperation programs with consideration of existing international mechanisms;
- ❖ promote scientific risk/benefit-based approaches to regulation of the self-medication industry;
- ❖ encourage communication about, and mutual understanding of each other's drug evaluation systems throughout the region;
- ❖ encourage potential collaboration on the use of Internet technology on therapeutic goods in the region;
- ❖ enhance and promote informed consumer access to self-medication and reasonable choice through truthful and valid advertising of self-medication products;

- ❖ ensure therapeutic goods policies are directed towards providing people with safe and effective medicines through attainment of a level of regulation appropriate to the assessed risk/benefit, while ensuring the timely availability of safe, high quality and effective therapeutic goods; and
- ❖ explore the establishment of a regional regulator's forum as a vehicle for future cooperation.

The participants at the Regulators' Forum agreed to encourage others associated with the advancement of public health to actively work towards successfully achieving positive outcomes in these areas.

In coming to these recommendations the Regulators' Forum carefully considered recent developments and approaches taken in the self-medication industry.

The Regulators' Forum acknowledged the *World Self-Medication Industry Guiding Principles* which suggests that more and more knowledgeable, responsible and motivated consumers are taking an active interest in their health. It was recognised and agreed that, because of this, governments should have sound policies in place that both allow and encourage responsible self-medication with products designed for such use.

The participants of the Regulators' Forum recognised the necessity and value of partnerships within the region and agreed to exchange more information with all stakeholders to ensure that government policies and directions adequately respond to the needs and desires of their people in the country and the greater community.

The participants at the Regulators' Forum also agreed to review the implementation of the recommendations of the Sydney 2000 Regulators' Forum next time they convene to ensure the longer term benefits from the close and productive work at the Sydney Forum are realised.

Terry Slater

*National Manager - Therapeutic Goods Administration Australia
& Chairman - Regulators' Forum (23 November 2000)*

Our Executive Director Looks Forward



The Australian Self-Medication Industry (ASMI) reached its first anniversary under our new name. I am happy to report that the spirit of renewal and vitality carried us to a very successful year.

The achievements listed in this Annual Report are certainly not an exhaustive report of all our activities on behalf of Industry, and are instead meant to be indicative of our focus on our four Strategic Objectives and our learnings from the Member Survey and many face-to-face meetings with Members held throughout the year.

Some highlights include:

On behalf of our world body, the World Self-Medication Industry (WSMI), we hosted a conference that attracted 400 participants from twenty-six countries. In unprecedented partnership, the Therapeutic Goods Administration was represented on our planning team for this major conference leading to exciting synergies and ultimately The Sydney Declaration, which advanced regional discussions among regulatory bodies and provides the platform for future achievements.

We transferred to electronic provision of information via e-mail and our expanded website, while helping Members with the transition by providing free seminars in Sydney and Melbourne.

We refocused the Secretariat to concentrate our strengths, address our weaknesses and ensure our sustainable future as the peak body in our sector.

Of course, there were several formal submissions made on behalf of industry:

- ❖ to the Regulatory Reform Taskforce in order to achieve improved efficiency at agency interfaces and reduced duplication,
- ❖ to the Productivity Commission Review on Cost Recovery Arrangements setting out that 100% cost recovery is inappropriate,
- ❖ to the Trans-Tasman Single Agency project generally supporting the proposal, and
- ❖ a pre-budget submission to the Federal Government calling for all medicines to be GST-free.

While last year we reported to you on the new Therapeutic Goods Advertising Code, the Galbally Review of drugs and poisons legislation and the beginnings of a whole-of-industry approach to Crisis Management and Tamper Evident Packaging, this year we can report on how the implementation is taking shape in these areas.

If asked what single message I would ask Members to interpret from our work this year, it would be that we are doing more for Members, not through increased fees (these, in fact, remain unchanged despite mergers and other financial pressures), but through expanded scope and improved systems designed with our core objectives in mind.

It is also my happy duty to report on future directions. As our annual conference attests, we are actively engaged in optimising our future potential as an industry. Fortuitously, I've been asked to speak at the Non-Prescription Medicines Association (NZ) Conference on industry's future. I will maintain to that audience that in the near future we will be faced increasingly with borderless markets, global cost pressures, emerging markets, and conflict between science and politics. These are not easy areas for a company to tackle alone—and our Members won't have to.

It will be a time of reshaping the self-care industry. In my view, we will need to harness our mutual goals, acknowledge that the consumer is king/queen, and accept the influence of Internet and address ourselves to it. In some cases, e-opportunities will be used to fulfill consumer needs. In all cases, the self-care process will become a more complex continuum:

Prevention – ailment – consultation – OTC treatment – appropriate use

What are the implications for industry? Well, they are certainly not that partnerships are less relevant, but rather that business excellence will depend increasingly on using Internet technologies to create value networks. Industry associations have a key role to play here. In addition, physical assets will become somewhat less valuable in the future while leveraging knowledge assets will be as, or even more, valuable. For this reason, your Association is due to become more important to your business in the future.

I say that because of the nature of the future itself. The children born now will reach what we now think of as retirement age at a time that it is predicted the population of the Earth will peak. Between now and then, the shifting demographics will be a trap for the unwary and an enormous opportunity for the most flexible companies.

In the next few years, the paradigm will complete its shift from the old view of a product as the ingredients it contains and the new view that the product is a combination of those ingredients and the information matrix provided by the manufacturer, health professional and the consumer's own information gathering. This becomes particularly interesting when considered in the context of the branded product vs the banner group product or the generic "equivalent".

Within a company, assets will be harder to quantify—the emerging employees in the future will not be stocktakers so much as information managers. Skills in effective communication, emerging technology, change management, demographic analysis and other such skills will not replace accountants and scientists, but the emphasis will shift. We have all read of the rise of the Chief Information Officer over the last half-decade.

We will see an increasingly sophisticated consumer, empowered by the availability of information, the accessibility of health professionals (and their demystification) and made worldly-wise by the knowledge that no paternalistic system can possibly look out for one as well as one can for oneself.

Industry is likely to feel the push to do a good job of informing consumers not only in the major language of a particular country but in a reasonable number of other prevalent languages. Industry will be asked what it is doing to solve its country's more intractable health challenges.

As home diagnostic technology marches on, and pharmacy monitoring of some chronic conditions becomes commonplace, we cannot help but be rewarded with the down-scheduling of certain products in those areas—if we are up to the associated responsibilities. If the consumer healthcare product sector is to branch out into chronic and recurrent conditions, we can expect—to borrow an American expression—to be asked to step up to the plate by government, health professionals and consumers. In particular—and this is happening already—industry will be asked to equip pharmacists to manage and make successful the down switching of a product from prescription to non-prescription status. This will involve education about both products and conditions.

In short, this is a time in which the opportunities are palpable, the threats are real and sobering, and the industry will be called upon to demonstrate its maturity. I for one am glad I have taken my vitamins!

To the future of our Industry,

Juliet Seifert
Executive Director

Major Enhancements to www.asmi.com.au

In time for the November 2000 conference, ASMI added a major new section to the website launched January 2000. This new section is password protected for the use of ASMI Members. Members made heavy use of this new resource and ASMI watched the hit rate climb with every passing month.

The new section has general information about the inner workings of the Association, material once provided in a hard-to-update paper format as the "PMAA Handbook", Member briefings, the full year's issues of ASMI publications such as the newsletters and Legislation Service, regulatory and technical guidelines and tips, and much more.

An extensive section on the National Packaging Covenant was also added. And offerings in the area of Quality Use of Medicine were widely expanded including all the core Consumer Medicine Information leaflets.

Navigation was improved by adding a search engine by Google, a portal page with an A to Z listing of popular site offerings, and a site map.

In all, the ASMI website has more than doubled in size this year.